

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2800
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94590

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item):

- ☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☒ C. RENEWAL OF LICENSE NUMBER 34-05382-01

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Marymount Hospital
12300 McCracken Rd.
Garfield Heights, OH 44125

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

SAME

8904050374 880401
REG3 LIC30
34-05382-01 PNU

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Vincent A. Gargaro, Universal Consultants, Inc.

TELEPHONE NUMBER

216 327-9432

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11 PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 7c AMOUNT ENCLOSED \$ 580.00

13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948; 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE - CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE President

DATE

Thomas J. Trudell

Thomas J. Trudell

and Chief Executive Off. 9-9-87

4. ANNUAL RECEIPTS

| | |
|---------------|-------------|
| < \$250K | \$1M - 3.5M |
| \$250K - 500K | \$3.5M - 7M |
| \$500K - 750K | \$7M - 10M |
| \$750K - 1M | > \$10M |

5. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

6. NUMBER OF BEDS

7. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Labor and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial - proprietary - information furnished to the agency in confidence)

☐ YES ☐ NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMOUNT RECEIVED

CHECK NUMBER

CONTROL NO. 84202 RECEIVED
SEP 24 1987

DATE

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY:** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S):** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30, 32, 33, 34, 35 and 40 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES:** The information may be (a) provided to State health departments for their information and use; and (b) provided to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION:** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.
5. **SYSTEM MANAGER(S) AND ADDRESS:** U.S. Nuclear Regulatory Commission
Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
Washington, D.C. 20555

MARYMOUNT NRC

| By Product Material | Amount | Purpose |
|-------------------------|-----------|-----------------------|
| 5.a. Material in 31.11 | as needed | 6.a. in Vitro testing |
| 5.b. Material in 35.100 | as needed | 6.b. Medical Use |
| 5.c. Material in 35.200 | as needed | 6.c. Medical Use |
| 5.c. Material in 35.300 | as needed | 6.d. Medical Use |

Items #5 & 6
Prepared: 8/17/87

CONTROL NO 84202

AUTHORIZED USERSBY PRODUCT MATERIAL

| | |
|-----------------------------------|---------------------------------|
| ✓ 1. NORBERT REICH, D.O. | 31.11, 35.100, 35.200 35.300 |
| ✓ 2. PAUL JANICKI, M.D. | 31.11, 35.100, 35.200 35.300 |
| ✓ 3. FRANK E. SEIDLEMANN, D.O. | 31.11, 35.100, 35.200 35.300 |
| ✓ 4. CHRISTINE A. QUINN, M.D. | 31.11, 35.100, 35.200 35.300 |
| ✓ 5. BYUNG H. WOO, M.D. | 31.11, 35.100, 35.200 35.300 |
| ✓ 6. THOMAS HAVRILLA, M.D. | 31.11, 35.100, 35.200 35.300 |
| ✓ 7. GUY SYVERTSEN, D.O. | 31.11, 35.100, 35.200 35.300 |
| ✓ 8. CLAUDIA ROZUK, M.D. | 31.11, 35.100, 35.200 35.300 |
| ✓ 9. CHRISTINE H. ECKHAUSER, M.D. | 31.11, 35.100, 35.200 35.300 |

For training and experience for users listed 1-7, refer to NRC license #34-05382-01.

For Claudia Rozuk, M.D. refer to NRC license #34-01334-02.

See attached for Christine H. Eckhauser, M.D.

Item #7
Prepared: 8/17/87

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

| | | | | |
|--------------------------------------------------------------------------------------------|------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------|----------------|
| 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER Christine H. Eckhauser, M.D. | | 2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE | | |
| 3. CERTIFICATION | | | | |
| SPECIALTY BOARD A | CATEGORY B | MONTH AND YEAR CERTIFIED C | | |
| | | | | |
| 4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES | | | | |
| FIELD OF TRAINING A | LOCATION AND DATE(S) OF TRAINING B | TYPE AND LENGTH OF TRAINING | | |
| | | LECTURE/ LABORATORY COURSES (Hours) C | SUPERVISED LABORATORY EXPERIENCE (Hours) D | |
| a. RADIATION PHYSICS AND INSTRUMENTATION | University Hospitals of Cleveland Cleveland, Ohio 44106 | 90 | 20 | |
| b. RADIATION PROTECTION | " | 30 | 10 | |
| c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY | " | 90 | 15 | |
| d. RADIATION BIOLOGY | " | 50 | 10 | |
| e. RADIOPHARMACEUTICAL CHEMISTRY | " | 40 | 5 | |
| 5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience) | | | | |
| ISOTOPE | MAXIMUM AMOUNT | WHERE EXPERIENCE WAS GAINED | DURATION OF EXPERIENCE | TYPE OF USE |
| I-131 | 200 mCi | University Hospitals of Cleveland | 3 months | Clin.Dx. & Rx. |
| Tc-99m | 1000 mCi | " | " | Clin.Dx. |
| P-32 | 30 mCi | " | " | " |
| Others | 10 mCi | " | " | " |

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

Christine H. Eckhauser, M.D.

STREET ADDRESS

56 Lyman Circle

CITY

STATE

ZIP CODE

Shaker Heights, Ohio 44122

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1-Supervised examination of patients to determine the suitability for radiolotope diagnosis and/or treatment and recommendation for prescribed dosage.

2-Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3-Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

| ISOTOPE | CONDITIONS DIAGNOSED OR TREATED | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) |
|----------------------|---------------------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| A | B | C | D |
| I-131 or I-125 | DIAGNOSIS OF THYROID FUNCTION | 80 | |
| | DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME | | |
| | LIVER FUNCTION STUDIES | | |
| | FAT ABSORPTION STUDIES | | |
| | KIDNEY FUNCTION STUDIES | 54 | |
| | IN VITRO STUDIES | | |
| OTHER | | | |
| I-125 | DETECTION OF THROMBOSIS | | |
| I-131 | THYROID IMAGING | 81 | |
| P-32 | EYE TUMOR LOCALIZATION | | |
| Se-75 | PANCREAS IMAGING | | |
| Yb-169 | CISTERNOGRAPHY | 9 | |
| Xe-133 | BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | 33 | |
| OTHER | Kidney Circulation | 47 | |
| Tc-99m | BRAIN IMAGING | 84 | |
| | CARDIAC IMAGING | 7 | |
| | THYROID IMAGING | | |
| | SALIVARY GLAND IMAGING | | |
| | BLOOD POOL IMAGING | 11 | |
| | PLACENTA LOCALIZATION | | |
| | LIVER AND SPLEEN IMAGING | 270 | |
| | LUNG IMAGING | 51 | |
| | BONE IMAGING | 380 | |
| OTHER | | | |

PRECEPTOR STATEMENT (Continued)

2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

| ISOTOPE A | CONDITIONS DIAGNOSED OR TREATED B | NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C | COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D |
|------------------------------------------------------|------------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| P-32 (Soluble) | TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES | 2 | <div data-bbox="1093 420 1527 796" data-label="Text"> <p><i>Not suitable for hyperthyroid need 10 mCi for each visit 300 p-32</i></p> </div> |
| P-32 (Colloidal) | INTRACAVITARY TREATMENT | | |
| I-131 | TREATMENT OF THYROID CARCINOMA | | |
| | TREATMENT OF HYPERTHYROIDISM | 5 | |
| Au-198 | INTRACAVITARY TREATMENT | | |
| Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | INTRACAVITARY TREATMENT | | |
| I-125 or Ir-192 or Co-60 or Cs-137 | INTERSTITIAL TREATMENT | | |
| | TELE THERAPY TREATMENT | | |
| Sr-90 | TREATMENT OF EYE DISEASE | | |
| | RADIOPHARMACEUTICAL PREPARATION | | |
| Mo-99/ Tc-99m | GENERATOR | 5 | |
| Sn-113/ In-113m | GENERATOR | | |
| Tc-99m | REAGENT KITS | 5 | |
| Other Ca67 Tl201 Co57 | Gallium Thallium Cardiac Schillings | 22 8 12 | |

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING

January 1981, February 1979 and March 1979

Total hours = 624

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

a. NAME OF SUPERVISOR

Abbas M. Rejali, M.D.

b. NAME OF INSTITUTION

University Hospitals of Cleveland

c. MAILING ADDRESS

2074 Abington Road

d. CITY

Cleveland, Ohio 44106

5. MATERIALS LICENSE NUMBER(S)

34-05469-01

6. PRECEPTOR'S SIGNATURE

Abbas M. Rejali

7. PRECEPTOR'S NAME (Please type or print)

Abbas M. Rejali, M.D.

8. DATE

May 8, 1987

Training for individuals working in or frequenting Restricted areas.

We will establish and implement the model training program that was published in Appendix A to Regulatory guide 10.8, Revision 2.

Ancillary personnel, e.g nursing, clerical, housekeeping, security, maintenance whose duties may require them to work in the vicinity of radioactive material will be given the opportunity to be informed about radioactive hazards and appropriate precautions.

Personnel will be instructed:

1. Before assuming duties with, or in the vicinity of, radioactive material.
2. During annual refresher training.
3. Whenever there is a significant change in duties, regulations, or in the terms of the license.

Facilities and Equipment

9.2 Survey meters will be calibrated by Universal Consultants, Inc., NRC license #34-20327-01.

9.3 We will establish and implement the model procedure for calibrating our dose calibrator that was published in the Appendix C to regulatory guide 10.8, Revision 2.

9.4 We will establish and implement the model personnel external exposure monitoring program published in the Appendix D to regulatory guide 10.8, revision 2.

Item #9
Prepared: 8/17/87

1. SMOKE DAMPERS WIRED
CLOSE VIA HALONE FIRE
TECTION SYSTEM. VERIFY
= ON SITE.

REFRIGERANT PIPING TO
OUTDOOR CONDENSING
UNIT - SEE 1/8" SCALE -

CORRIDOR

N.M.1

CLOSET

N.M.2

A.C. UNIT No. 1
MOUNT TO FIT
CEILING GRID.
PIPE 3/4" D. TO F.D.
FOR CONDENSER
LOCATION
- SEE 1/8" SCALE -

RELOCATE EXIST'G
OUTLETS AS REQ'D
TO FIT NEW GRID

RELOCATE EXIST'G
OUTLET AS REQ'D
TO FIT NEW GRID

NUCLEAR RM.

SIM.3

CONTROL RM.

N.M.4

- a.) lead lined
storage bin
16"x24"x2"
- b.) L block
8"x12"x2"
- c.) Picker well
system



Partial First Floor Plan - H.V.A.C.

Nuclear Med. Unit

scale: 1/4" = 1' - 0"

10.1 We will establish and implement the model procedure for establishing and operating a Radiation Safety Committee that was published in Appendix F to regulatory guide 10.8, Revision 2.

10.2 We will establish and implement the model ALARA program that was published in Appendix G to regulatory guide 10.8, Revision 2.

10.3 Leak test will be performed by U.C.I., license #34-20327-01.

10.4 We will establish and implement the model safety rules that was published in Appendix I guide 10.8, Revision 2.

10.5 We will establish and implement the model spill procedures published in Appendix J guide 10.8, Revision 2.

10.6 We will establish and implement the model guidelines for ordering and receiving radioactive material that was published in Appendix K guide 10.8, Revision 2.

10.7 We will establish and implement the model procedures for opening packages that was published in Appendix L guide 10.8, Revision 2.

10.8 We will establish and implement the model procedure for unit dosage record system that was published in Appendix M.1 guide 10.8, Revision 2.

10.9 We will establish and implement the procedure for multidose vial record that was published in Appendix M.2 guide 10.8, Revision 2.

10.10 We will establish and implement the model procedure for measuring and recording molybdenum concentrations that was published in Appendix M.3 guide 10.8, Revision 2.

10.11 N/A

10.12 We will establish and implement the model procedure for area surveys that was published in Appendix N guide 10.8, Revision 2.

10.13 N/A

10.14 We will establish and implement the model procedure for radiation safety during radiopharmaceutical therapy that was published in Appendix P guide 10.8, Revision 2.

10.15 N/A

Item #10
Prepared: 7/18/87

11.1 We will establish and implement the general guidance and model procedure for waste disposal that were published in Appendix R guide 10.8, Revision 2.
The used radiopharmaceuticals may be returned to Central radiopharmacy.

For items 5 through 11 refer to attached sheets.

Item #11
Prepared: 7/18/87

CONTROL NO. 84202

DEC 29 1986

Marymount Hospital
ATTN: Thomas J. Trudell
President and Chief Executive
Officer
12300 McCracken Boulevard
Garfield Heights, OH 44125

Gentlemen:

Enclosed is Amendment No. 33 to your NRC License No. 34-05382-01 in accordance with your request.

Please note the Subitems 6.C., 7.C., 8.C., and 9.C., pertaining to xenon-133 use at your facility have been deleted as requested.

Please review the enclosed document carefully and be sure that you understand all conditions. You must conduct your program involving radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Possess radioactive material only in the quantity and form indicated in your license.
3. Use radioactive material only for the purpose(s) indicated in your license.
4. Notify NRC in writing of any change in mailing address.
5. Request and obtain appropriate amendment if you plan to change ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. Any amendment request should be accompanied by the appropriate fee specified in 10 CFR Part 170.

8764010587 861229
REG3 LIC30
34-05382-01 PDR

288

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of radioactive material after your license expires is a violation of NRC regulations.
7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material prior to your expiration date.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions and representations in your license application will result in enforcement action against you in accordance with the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

If you have any questions or require clarification of any of the above stated information, contact us at (312) 790-5625.

Sincerely,

Original Signed By
Cassandra F. Frazier
Materials Licensing Section

Enclosure: Amendment No. 33

RIII

Frazier/pd
12/ /86

| | | |
|---------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------|
| NRC FORM 313M (9-81) 10 CFR 35 | U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL | Approved by OMB 3150-0041 |
|---------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------|

INSTRUCTIONS - Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.a. NAME AND MAILING ADDRESS OF APPLICANT (institution, firm, clinic, physician, etc.) INCLUDE ZIP CODE Marymount Hospital 12300 McCracken Blvd. Garfield Hts., OH 44125 TELEPHONE NO.: AREA CODE <u>216</u> <u>581</u> <u>0500</u> | 1.b. STREET ADDRESS(ES) (WHICH RADIOACTIVE MATERIAL WILL BE USED (if different from 1.a.) INCLUDE ZIP CODE Same 2. PERSON TO CONTACT REGARDING THIS APPLICATION W. Christopher Wagner, Consultant NMA Medical Physics Services TELEPHONE NO.: AREA CODE <u>216</u> <u>641</u> <u>5799</u> |
| 4. INDIVIDUAL USERS (Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.) Refer to attached Item #8 | 3. THIS IS AN APPLICATION FOR: (Check appropriate item) a. <input type="checkbox"/> NEW LICENSE b. <input checked="" type="checkbox"/> AMENDMENT TO LICENSE NO. <u>34-05382-01</u> c. <input type="checkbox"/> RENEWAL OF LICENSE NO. _____ 5. RADIATION SAFETY OFFICER (RSO) (Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.) Frank Seidelman, D.O. with NMA Medical Physics Services as Consultants |

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

| RADIOACTIVE MATERIAL LISTED IN: | ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS (In millicuries) | ADDITIONAL ITEMS: | MARK ITEMS DESIRED "X" | MAXIMUM POSSESSION LIMITS (In millicuries) |
|--------------------------------------|----------------------|-----------------------------------------------|-----------------------------------------------------------------------------------------------------|---------------------------|-----------------------------------------------|
| 10 CFR 31.11 FOR IN VITRO STUDIES | | | IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM | | |
| 10 CFR 35.100, SCHEDULE A, GROUP I | | AS NEEDED | PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES | | |
| 10 CFR 35.100, SCHEDULE A, GROUP II | | AS NEEDED | PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| 10 CFR 35.100, SCHEDULE A, GROUP III | | | GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS. | | |
| 10 CFR 35.100, SCHEDULE A, GROUP IV | | AS NEEDED | IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA | | |
| 10 CFR 35.100, SCHEDULE A, GROUP V | | AS NEEDED | XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES | | |
| 10 CFR 35.100, SCHEDULE A, GROUP VI | | | | | |

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. (Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)

| ELEMENT AND MASS NUMBER | CHEMICAL AND/OR PHYSICAL FORM | MAXIMUM NUMBER OF MILLICURIES OF EACH FORM | DESCRIBE PURPOSE OF USE |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------------------------|-------------------------|
| The purpose of this application is to amend for the following items: 1. To include Guy Syverston, D.O. as an authorized user. 2. Note camera equipment change. 3. Department relocation (Note: Xenon-133 will not be utilized in the new department... Please delete institutional authorization.) | | | |

8704010593 861229
 REG3 LIC30
 34-05382-01 PDR

10 PP.

RECEIVED
 NOV 28 1986
 REGION III

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

| | | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------------|
| 7. MEDICAL ISOTOPES COMMITTEE | | 15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One) | |
| <input type="checkbox"/> | Names and Specialties Attached; and | <input type="checkbox"/> | Appendix G Rules Followed; or |
| <input type="checkbox"/> | Duties as in Appendix B; or _____ (Check One) | <input type="checkbox"/> | Equivalent Rules Attached |
| <input type="checkbox"/> | Equivalent Duties Attached | 16. EMERGENCY PROCEDURES (Check One) | |
| 8. TRAINING AND EXPERIENCE | | <input type="checkbox"/> | Appendix H Procedures Followed; or |
| <input type="checkbox"/> | Supplements A & B Attached for Each Individual User; and | <input type="checkbox"/> | Equivalent Procedures Attached |
| X | Refer to attached Item #8 Supplement A Attached for RSO. | 17. AREA SURVEY PROCEDURES (Check One) | |
| 9. INSTRUMENTATION (Check One) | | <input type="checkbox"/> | Appendix I Procedures Followed; or |
| X | Appendix C Form Attached; or | <input type="checkbox"/> | Equivalent Procedures Attached |
| <input type="checkbox"/> | List by Name and Model Number | 18. WASTE DISPOSAL (Check One) | |
| 10. CALIBRATION OF INSTRUMENTS | | <input type="checkbox"/> | Appendix J Form Attached; or |
| <input type="checkbox"/> | Appendix D Procedures Followed for Survey Instruments; or _____ (Check One) | <input type="checkbox"/> | Equivalent Information Attached |
| <input type="checkbox"/> | Equivalent Procedures Attached; and | 19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS (Check One) | |
| <input type="checkbox"/> | Appendix D Procedures Followed for Dose Calibrator; or _____ (Check One) | <input type="checkbox"/> | Appendix K Procedures Followed; or |
| <input type="checkbox"/> | Equivalent Procedures Attached | <input type="checkbox"/> | Equivalent Procedures Attached |
| 11. FACILITIES AND EQUIPMENT | | 20. THERAPEUTIC USE OF SEALED SOURCES | |
| X | Description and Diagram Attached | <input type="checkbox"/> | Detailed Information Attached; and |
| 12. PERSONNEL TRAINING PROGRAM | | <input type="checkbox"/> | Appendix L Procedures Followed; or _____ (Check One) |
| <input type="checkbox"/> | Description of Training Attached | <input type="checkbox"/> | Equivalent Procedures Attached |
| 13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL | | 21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon - 133) | |
| <input type="checkbox"/> | Detailed Information Attached | <input type="checkbox"/> | Detailed Information Attached |
| 14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS (Check One) | | 22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS | |
| <input type="checkbox"/> | Appendix F Procedures Followed; or | <input type="checkbox"/> | Detailed Information Attached |
| <input type="checkbox"/> | Equivalent Procedures Attached | 23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b | |
| <input type="checkbox"/> | | <input type="checkbox"/> | Detailed Information Attached |

24. PERSONNEL MONITORING DEVICES

| TYPE <small>(Check appropriate box)</small> | | SUPPLIER | EXCHANGE FREQUENCY |
|------------------------------------------------|-----------------|----------|--------------------|
| a. WHOLE BODY | FILM | | |
| | TLD | | |
| | OTHER (Specify) | | |
| b. FINGER | FILM | | |
| | TLD | | |
| | OTHER (Specify) | | |
| c. WRIST | FILM | | |
| | TLD | | |
| | OTHER (Specify) | | |
| d. OTHER (Specify) | | | |

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

| | | |
|-------------------------------------------------------------------------|-------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL | | b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR. |
| NAME OF HOSPITAL | | c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS. |
| MAILING ADDRESS | | |
| CITY | STATE ZIP CODE | |

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

| | |
|----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| a. LICENSE FEE REQUIRED <small>(See Section 170.31, 10 CFR 170)</small> | b. APPLICANT OR CERTIFYING OFFICIAL (Signature) <div style="text-align: center;"> (1) NAME (Type or Print) X Thomas J. Trudell </div> |
| (1) LICENSE FEE CATEGORY: | (2) TITLE X President & Chief Exec. Officer |
| (2) LICENSE FEE ENCLOSED: \$ 120.00 | c. DATE X November 26, 1986 |

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).
2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.
3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.
4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.
5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

NAME OF AUTHORIZED USER

AUTHORIZATION

Amend to add:

Guy R. Syverston, D.O.

Groups I, II, III

Iodine-131 for treatment
of hyperthyroidism and
cardiac dysfunction.

For physician training and experience, please refer to NRC
license #34-17835-01.

Item #8
1 of 1 page
Prepared: 10/1/86
Lic. # 34-05382-01

APPENDIX C INSTRUMENTATION

1. Survey meters (Amend to add)

- a. Manufacturer's name: Bicron
 Manufacturer's model number: Surveyor 50
 Number of instruments available:
 Minimum range: 0 mR/hr to 0.5 mR/hr
 Maximum range: 0 mR/hr to 50 mR/hr
- b. Manufacturer's name:
 Manufacturer's model number:
 Number of instruments available:
 Minimum range: mR/hr to mR/hr
 Maximum range: mR/hr to mR/hr

2. Dose Calibrator(s)

Manufacturer's name:
 Manufacturer's model number:
 Number of instruments available:

3. Instruments used for diagnostic procedures

| Type of Instrument | Manufacturer's Name | Model No. |
|-------------------------|---------------------|-----------|
| <u>Amend to add:</u> | | |
| Scintillation camera | Picker | 5X300 |
| <u>Amend to delete:</u> | | |
| Scintillation camera | Siemens | 37GP |
| Scintillation camera | Siemens | LFOV |

4. Other (e.g., liquid scintillation counter, area monitor, velometer)

Item #9
 1 of 1 page
 Prepared: 10/1/86
 Lic. #34-05382-01

FACILITIES AND EQUIPMENT DESCRIPTION

All radioactive sources are stored in such a manner (lead, concrete, refrigerator) so as to not exceed 2mR/hr at the surface of the barrier.

Mo-99/Tc-99m generator when used will be stored and eluted in the designated area. It will be shielded with lead bricks such that levels from all avenues of approach do not exceed 2.0mR/hr. Spent generators will be stored in the location identified in the attached diagram.

During elution, the eluate will be collected, assayed, and stored in a vial held in a quarter inch lead pig except during brief periods of transfer. Transfer of the eluate or portions of the eluate will be made by the use of syringes retained in lead shields designed for this purpose.

Eluates and compounds made from eluates will be drawn, synthesized, assayed and stored in lead vials or syringes such that levels as measured at contact with a low level survey meter do not exceed 2.0mR/hr except for brief periods during the actual transfer.

Radioactive materials obtained from radiopharmacy suppliers will be stored in their original shipping containers. If necessary, the doses will be placed behind additional shielding to reduce activity levels emitted from the container to 2mR/hr or less.

Syringe shields will be used on all accessories requiring the transfer of radiopharmaceuticals from vial to vial and in drawing up patient doses. Syringe shields will also be used in the administration of doses to patients except when the patient's well-being may be compromised. Under these circumstances, the dose containing syringes will be kept shielded up to the moment of injection.

Steps in the preparation of compounds requiring periods of heating, shaking, agitation or mixing will be performed utilizing lead shielding and/or mechanical or ultrasonic agitation equipment and/or remote handling devices (tongs, forceps, etc.) such that levels during the above period as measured by a low level survey meter do not exceed 2.0mR/hr.

Protective outer garments, such as laboratory coats and rubber gloves will be worn while handling radioactivity in uncontained form.

Item #11
1 of 4 pages
Prepared: 10/1/86
Lic. # 34-05382-01

All possible set-ups will be made on easily cleanable trays. All trays and all other work surfaces will be covered with disposable absorbent paper.

A decontamination kit will be maintained in the department. It will include the following items:

DECONTAMINATION KIT

| <u>ITEM</u> | <u>PURPOSE</u> |
|--------------------------------|--------------------------------------------|
| 1. Warning tape, chalk & signs | posting of area |
| 2. Plastic bags, small | shoe covers, wet containers |
| 3. Disposable gloves | hand protection |
| 4. Masking tape | fasten shoe covers, etc. |
| 5. Forceps, tongs | safe handling |
| 6. Large plastic bags | for contaminated material |
| 7. Sponges, 4 x 4 | sopping up |
| 8. Paper towels | blotting & drying |
| 9. Radiac wash or detergent | detergent |
| 10. Scouring powder | friction |
| 11. Tags | identification |
| 12. Scissors | cut absorbent paper, etc. |
| 13. Whatman #1 filter paper | taking swipes following decontamination |
| 14. Chux | cover area following decontamination |
| 15. G-M survey meter | monitoring |

Item #11
2 of 4 pages
Prepared: 10/1/86
Lic. # 34-05382-01

FACILITIES AND EQUIPMENT DIAGRAM



Air Supply



Air Exhaust



Sink



Lead Castle

Lead Shielding

Adjacent Areas

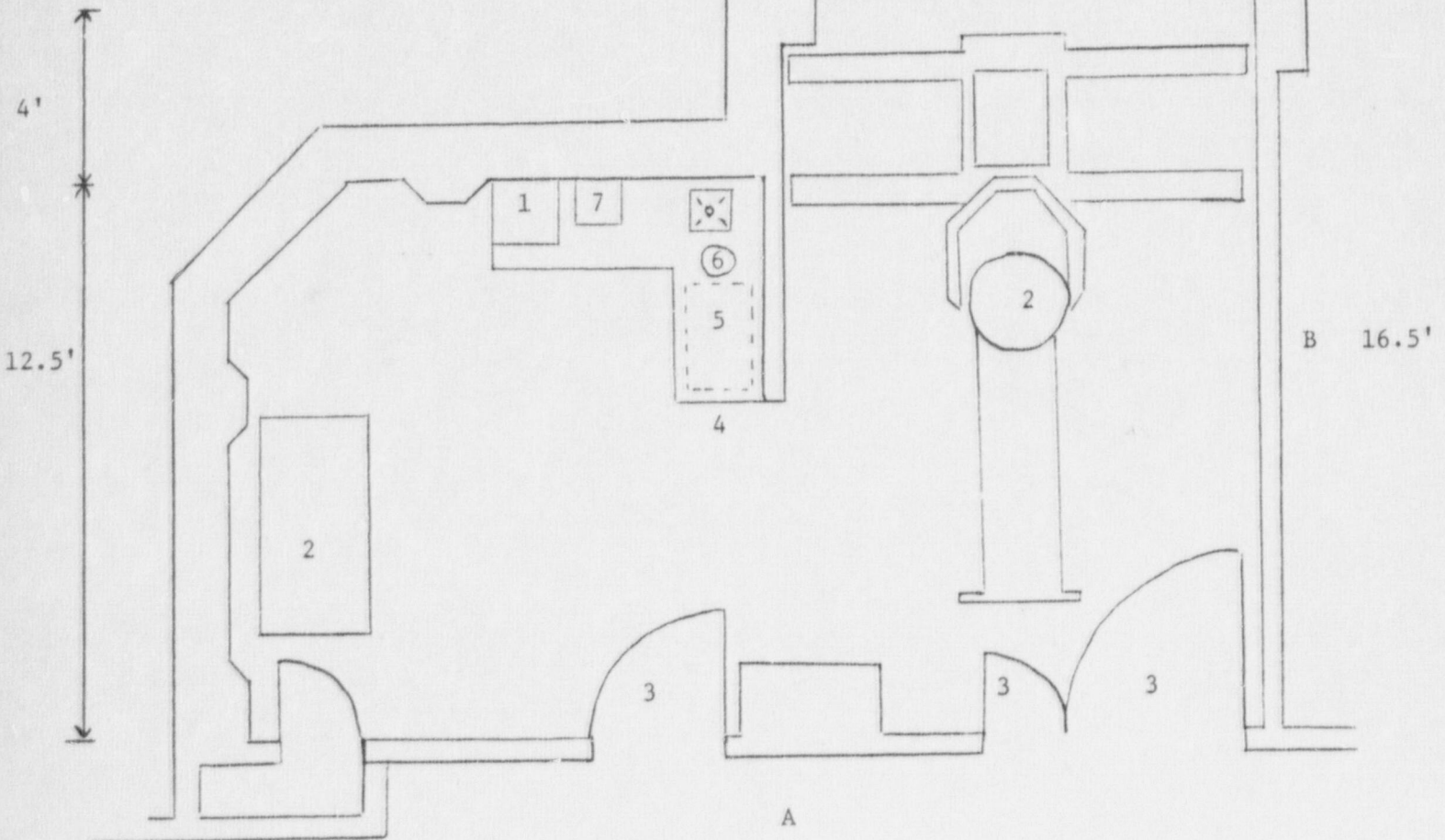
| | |
|------------------------------------|-----------|
| Scanner | |
| 1 Uptake/Well | |
| 2 Camera/Console | A Hallway |
| 3 Lockable Door | B Office |
| 4 Receipt Area | |
| Generator (Radiopharmacy Utilized) | |
| 5 Kit Preparation | |
| 5 Isotope Storage | |
| 5 Dose Preparation | |
| 5 Waste Storage | |
| 6 Dose Calibrator | |
| Refrigerator | |
| 7 Computer | |

5
 12 "L x 16 "W x 12 "H x 2 "T
 5 Standard L Shield
 "L x "W x "H x 1/2 "T

"L x "W x "H x "T

"L x "W x "H x "T

12.5' 10.5'



Note that this is a new department for nuclear medicine. A close-out survey will be performed on the old department consisting of exposure rate measurements at all places where radioactive materials were used or stored. The average radiation levels associated with surface contamination or removable contamination will not exceed background. The survey will consist of the following:

- a. A diagram of the old facility with survey and wipe test results keyed to specific locations.
- b. The name of the person performing the survey.
- c. Date the survey was performed.
- d. The instrument(s) used for exposure rate measurements and analysis of wipes.
- e. Instrument calibration date.
- f. Background information.

The results of the close-out survey will be reviewed by our consultants (MMA Medical Physics Services) and retained in the department for future reference.

Item #11
Page 4 of 4
Prepared: 10/1/86
Lic.#34-05382-01

CONTROL NO. 82536